

### **Remarks**

The present response is being submitted in reply to the Office action issued on March 31, 2005. Claims 33-40 are pending in this application, while claims 8-14, 23 and 26-32 are withdrawn from consideration. By the present response, claims 33, 34, 39 and 40 have been amended and new claims 41-43 have been added. New claims 41-43 correspond to claims 33, 34 and 40 and further recite the types of polymers used in the three layers of the therapeutic system. Support for these limitations can be found in the original disclosure at pages 10-12 under the section "Example." No new matter has been added. In addition, claims 8-14, 23 and 26-32, which had been withdrawn from consideration, are canceled by the present response. Each of these claims is present in co-pending application Serial No. 10/991,713, which is a divisional application based on the instant application. Reconsideration is respectfully requested in light of the amendments being made hereby and of the following remarks.

### **Request for Information Rule 1.105**

The Examiner has noted U.S. Patent No. 5,023,084 (Chien, et al.) as a reference of interest in that it may anticipate the instant invention. However, the Examiner was not able to ascertain the glass transition temperature of Duro-Tak 80-1054 and BASO Oppanol B80 and requested that the applicant provide this information to the Examiner.

The applicant first notes that no direct information could be found for the glass transition temperature of Duro-Tak 80-1054. It appears that this particular product may not be marketed under this product name anymore. However, U.S. Patent No. 5,840,052 (Johns) indicates that this adhesive has a viscosity of 3,000 cps (col. 7, lines 20-25).

Duro-Tak types which are currently marketed by National Starch & Chemical and which have similar properties to Duro-Tak 80-1054 (i.e., viscosity) are Duro-Tak 387-2052 and 387-2054. These latter two types of adhesives have a theoretical glass transition temperature of -50°C. Other Duro-tak types, such as 387-2287, have a higher viscosity, and therefore, a higher glass transition temperature. The applicant has enclosed herewith a data sheet pertaining to Duro-Tak 387-2287 for the Examiner's reference and comparison to Duro-Tak 80-1054.

Oppanol B80 has a glass transition temperature of -63°C according to the technical information provided by the manufacture. A copy of this data sheet is also enclosed for the Examiner's reference.

As set forth in the Office action, the Examiner states that Chien, et al. may anticipate the present invention since the reference discloses a first adhesive layer that contains estrogen and a pressure sensitive adhesive, wherein the pressure sensitive polymer has a  $T_g$  below room temperature, a separating layer containing polyisobutylene polymer and a third adhesive layer that contains progestin and a pressure sensitive adhesive wherein the pressure sensitive adhesive polymer has a  $T_g$  below room temperature. The Examiner notes that the specific glass transition temperatures of Duro-Tak and Oppanol B80 are not provided for the determination as to whether the reference anticipates the present invention. The Examiner further notes that the separating layer of Chien, et al. corresponds to the  $T_g2$  – containing layer of the instant invention. This layer contains polyisobutylene polymer (Oppanol B80) having a glass transition temperature of -63°C, whereas the other two layers of the trilayer are based on Duro-Tak 80-1054. The

applicant respectfully submits that from what is known about the glass transition temperatures of similar Duro-Tak adhesives, it must be assumed that the glass transition temperature of Oppanol B80 is lower than the glass transition temperature of Duro-Tak 80-1054. Therefore, Chien, et al. does not anticipate the instant claims. Withdrawal of this patent as the basis of a possible anticipation rejection is respectfully requested.

**Rejection of claims 33-40 under 35 U.S.C. 112, first paragraph**

Claims 33-40 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Examiner states that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner states that claims 33-40 recite a system containing “at least three polymer layers,” but that the specification provides support for “at least two polymer layers.” The applicant submits that the claims have been amended to recite “three polymer-containing layers” rather than “at least three polymer layers.” Withdrawal of this rejection is respectfully requested.

The Examiner also states that the recitation “the glass transition temperature Tg1 ...are identical *or different*...” does not have support since there is only support for the first layer and third layer having identical glass transition temperatures. Therefore, the Examiner considers the term “or different” to be new matter.

The applicant respectfully disagrees and submits that the original disclose provides support for this claim limitation at page 9, lines 1-2, page 10, lines 1-5 and also in claim 1, as originally filed. In each instance, the specification states “the layers differ

in their glass transition temperature.” Withdrawal of this rejection is respectfully requested.

**Rejection of claims 33-40 under 35 U.S.C. 103(a)**

Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka et al.) by itself or in view of U.S. Patent No. 6,063,838 (Patnode, et al.). According to the Examiner, Otsuka teaches a pressure sensitive adhering composite medicinal preparation to provide drug supply to the skin comprising every limitation set forth in claims 33-40, except for the third layer. The Examiner states that although Otsuka, et al. suggests more than two polymer layers, the reference does not exemplify the third layer. It is the Examiner’s position that it would have been obvious to one skilled in the art to refer to Otsuka, et al. and incorporate a third polymer-containing layer with the motivation being that Otsuka, et al. teaches that the composite should contain at least two layers.

The Examiner further refers to Patnode, et al. for the teaching of a blended pressure-sensitive adhesive which is formed from at least two polymeric materials wherein at least one is a pressure sensitive adhesive. The Examiner further states that the reference teaches an embodiment wherein a multilaminate device contains a backing, an adhesive layer which contains the drug and excipients, a membrane that controls the rate at which the drug is diffused to the skin, a second adhesive layer and a release layer. The Examiner concludes that it would have been obvious to one skilled in the art to combine the teachings of Otsuka, et al. and Patnode, et al. to utilize a third layer and to arrive at the present invention as set forth in claims 33-40.

Claims 33-40 are also rejected as being unpatentable over Otsuka, et al. by itself or in view of U.S. Patent No. 5,023,084 (Chien, et al.). As mentioned above, the Examiner states that Otsuka, et al. teaches every limitation of claims 33-40 but does not exemplify the third layer. It is the Examiner's position that it would have been obvious to one skilled in the art to refer to Otsuka, et al. and incorporate a third polymer-containing layer with the motivation being that Otsuka, et al. teaches that the composite should contain at least two layers.

The Examiner further refers to Chien, et al. for the teaching of a transdermal system that provides a combination of drugs (estrogen and progestin) in a unit dosage. According to the Examiner, Example 8 of Chien, et al. teaches that the transdermal contains a first adhesive layer that contains the estrogen and a pressure sensitive adhesive, a separating layer containing polyisobutylene polymer and a third adhesive layer that contains the progestin and a pressure sensitive adhesive. The Examiner concludes that it would have been obvious to one skilled in the art to combine the teachings of Otsuka, et al. and Chien, et al. to utilize another macromolecular layer which has a lower glass transition temperature than the polymer layer, thereby arriving at the present invention as set forth in claims 33-40.

The applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all of the claim limitation. Applicant respectfully

submits that one skilled in the art would have no suggestion or motivation to combine the aforementioned references in order to arrive at the present invention. Additionally, even if one skilled in the art were to consider Otsuka et al. alone, or in combination with either of Patnode, et al. or Chien, et al., each and every limitation of the present invention would not be disclosed, nor would there be a reasonable expectation of success if the aforementioned references were to be considered.

The applicant first submits that Otsuka, et al. does not disclose an arrangement as set forth in the instant claims. Specifically, Otsuka, et al. does not teach an active substance-containing therapeutic system in which a layer containing a polymer with a relatively high glass transition temperature (Tg2) is “sandwiched” between two layers containing polymers with relatively low glass transition temperatures (Tg1, Tg3). Moreover, the applicant submits that the “at least two layers” as taught by Otsuka, et al. may not indicate that the further layer(s) are additional adhesive layers. For example, the additional layer(s) of “at least two layers” of Otsuka, et al. could indicate the presence of non-adhesive layers such as a membrane (as disclosed by Patnode, et al.) and discussed below. Therefore, Otsuka, et al. has deficiencies in addition to those established by the Examiner in the Office action.

As explained above, the Examiner cites Patnode, et al. for combining with Otsuka, et al. to teach a third layer. However, in the multilaminate device shown in Figure 15 of Patnode, et al. a membrane 55 is interposed between the adhesive layers 56 and 57.

Claims 33-40, as presently amended, and new claims 41-43, recite that the layers

are laminated on top of each other. This arrangement allows the surface of the layers to interact with each other, thus suppressing cold flow. Support for this feature of the present invention may be found in the original disclosure at page 10, lines 1-5. Patnode, et al. does not disclose three layers laminated on top of each other and interacting with each other in the manner set forth in present claims 33-43 and so does not make up for the aforementioned deficiencies of Otsuka, et al. In turn, the present invention could not have been rendered obvious by the combination of teachings of Otsuka, et al. with Patnode, et al. Still further, Patnode, et al. fails to provide any specific information concerning the position of the third layer relative to the other two layers and the polymer composition (Tg) of this third layer.

In light of the aforementioned deficiencies of the combination of teachings of Otsuka, et al. and Patnode, et al., the applicant respectfully submits that the combination of references fails to teach every limitation set forth in claims 33-43 and that due to these deficiencies, one skilled in the art would not have been motivated to combine these references to arrive at the present invention. Withdrawal of this rejection is strongly requested.

Turning now to the second rejection under Section 103(a), the applicant respectfully disagrees for at least the aforementioned deficiencies of Otsuka, et al. Furthermore, Chien, et al. teaches a transdermal system comprising an intermediate (separating) layer which is based on Oppanol B80 and which appears to have a lower (emphasis added) glass transition temperature relative to the glass transition temperature of the adjacent layers of the polyacrylic adhesive. As set forth in present claims 33-43,

Tg2 is greater than (emphasis added) Tg1 and Tg3. Therefore, since this separating layer (which corresponds to the Tg2-containing layer of the present invention) contains a polymer having a lower glass transition temperature, the applicant submits that one skilled in the art would not have been motivated to combine this teaching with Otsuka, et al., to arrive at the present invention and even if such a combination were made, every limitation of instant claims 33-43 would not be taught or disclosed. Moreover, the applicant respectfully submits that the combination of teachings teaches away from the present invention as set forth in the instant claims since it would teach a Tg2 that is lower than Tg1 and Tg3, instead of being greater.

The applicant further submits that the teaching of Example 8 of Chien, et al. is not relevant for new claims 41-43 wherein which all three layers contain acrylic polymers. Contrastly, the separating layer of Example 8 is based on polyisobutylene. In light of these deficiencies of the combination of the teachings of Otsuka, et al. and Chien, et al., the applicant respectfully submits that the combination of references fails to teach every limitation set forth in claims 30-42 and that due to these deficiencies, one skilled in the art would not have been motivated to combine these references to arrive at the present invention. Withdrawal of this rejection is strongly requested.

### **Conclusion**

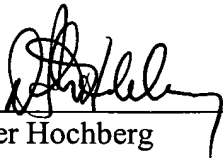
In light of the foregoing claims and arguments, it is believed that the present application is in condition for allowance, and such action is earnestly solicited. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.



Respectfully submitted,

Date: June 29, 2005

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